

**REMARKS**

Reconsideration of the present application in view of the following remarks is respectfully requested. Claims 2, 3, 73-75 and 77-109 are currently pending and under consideration. Claims 73, 94, 96-98, 100, 108 and 110 are amended. Claims 110-116 have been withdrawn from consideration and claims 1, 4-72 and 76 have been cancelled.

The outstanding Action dated December 11, 2008, is a Non-final Action.

**Objections to Specification (Including Drawings)**

The outstanding Action objects to the specification on multiple grounds. The Action requires amendment of the "Cross-Reference to Related Applications" section to correct an alleged error regarding the CIP status of U.S. patent application serial no. 08/740,031 and to update the status of U.S. patent application serial no. 10/114,675. Applicants have above amended the Cross-Reference to Related Applications section to update the status of application serial no. 10/114,675 and also to update the status of application serial no. 08/603,676; however, Applicants traverse the objection to the specification based upon the assertion that the CIP status of U.S. patent application serial no. 08/740,031 is in error.

With regard to the alleged error regarding the CIP status of U.S. patent application serial no. 08/740,031, the Action asserts that, "Contrary to what is asserted at the beginning of the specification (as amended by the Preliminary Amendment of February 18, 2004), there is no evidence from USPTO PALM records or from Applicant's own U.S. 6,371,988 B1 that U.S. patent application serial no. 08/740,031 is a continuation-in-part of U.S. patent application serial no. 08/603,676." In response, the undersigned is investigating the priority information for the applications identified in the Action; however, because the undersigned has not yet been able to obtain certain pertinent records, this investigation has not yet been completed. At present, Applicants continue to believe that U.S. patent application serial no. 08/740,031 is a continuation-in-part of U.S. patent application serial no 08/603,676, and that the USPTO PALM records might be incomplete

or incorrect. Applicants will supplement this response as appropriate after further investigation of this issue is completed.

In addition, the specification and the drawings are objected to in the Action because of several informalities, as listed on page 2 of the Action. These objections to the specification and the drawings have been addressed by the amendments presented above, and by the corrected drawings for Figures 1, 35, 37 and 49 submitted herewith. Specifically with regard to the drawings, Applicants have modified Figure 1 to add reference numerals 11, 12 and 13. Applicants have also modified Figure 35 to show threading for tool engaging hole 174, and to add reference numeral 178 to identify the threading as described at page 24 of the application. Applicants have also modified Figure 37 to correct the placement of the lead line for feature 226. Finally, Applicants have modified Figure 49 to change reference numeral "30" to "32". Applicants are believed to have addressed each of the specification and drawing objections set forth in the Office Action, and withdrawal of the same is respectfully requested.

#### **Objection to Claim 108**

Claim 108 is objected to in the outstanding Action because of an informality. In view of the amendment to claim 108 presented above, Applicants submit that this objection is overcome.

#### **Double Patenting**

Claims 2, 3, 73-75, 77-102 and 104-109 stand rejected on the ground of non-statutory obviousness-type double patenting over the claims of U.S. Patent No. 6,371,988. Since these claims have not been indicated to be otherwise allowable in this application, Applicants will defer submission of a terminal disclaimer at this time and until one or more of claims 2, 3, 73-75, 77-102 and 104-109 are otherwise indicated to be allowable.

### **Art Rejections**

Of the claims pending in the present application, the independent claims are claims 73 and 94. Claim 73 is rejected in the outstanding Office Action under 35 U.S.C. 102(b) as being anticipated by Wayne, EP 0 567 391 A1 (hereafter “Wayne”) and as being anticipated by Bruce et al., EP 0 585 168 A2 (hereafter “Bruce”). In addition, both of independent claims 73 and 94 are rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,814,084 to Grivas et al. (hereafter “Grivas”) in view of Wayne and Bruce. Each of the two independent claims is discussed separately below.

#### **Independent claim 73**

It is well established that “an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim.” *Richardson v. Suzuki Motor Co. Ltd.*, 9 USPQ.2d 1913, 1920 (Fed. Cir. 1989).

Claim 73 has been amended herein to more particularly specify that the “bone dowel” recited therein comprises “a cortical bone section cut from a bone of a donor,” and further recites, “said cortical bone section having impregnated therein an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor.” Support for the amendment to independent claim 73 is found, for example, at page 13, lines 25-27; page 14, lines 27-29; and page 19, lines 7 and 21 of the as-filed application. Applicants submit that the subject matter of claim 73 is novel over Wayne and Bruce because neither of these references describes a device that includes “a cortical bone section having impregnated therein an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor” as recited in claim 73, as amended.

Wayne describes a biodegradable composition that “contains a mixture of demineralized bone matrix (DBM) and a degradable homopolymer or copolymer, such as poly (lactic-co-glycolic acid) (PLPG), in which TGF- $\beta$  is dissolved or dispersed.” (column 3, lines 43-46). As stated in Wayne, “Demineralized bone matrix (DBM) is a bone

derivative that is prepared by demineralizing cadaver bone with HCl.” (column 2, lines 1-3). As described at column 6, line 13, to column 7, line 9, the biodegradable composition described in Wayne can be formed into a desired shape by solvent casting or compression molding, each of which combines DBM powder with other ingredients and then forms the composition into a desired shape.

Wayne does not, however, describe a device that includes “a cortical bone section cut from a bone of a donor, said cortical bone section having impregnated therein an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor” as recited in claim 73, as amended.

Bruce describes compositions “containing demineralized bone matrix and TGF- $\beta$  [that] can be used to stimulate the development of bone in areas of the body where new bone formation is desired.” (page 4, lines 8-10). As stated in Bruce, “The DBM of the present invention is a bone derivative prepared by demineralizing bone with HCl, followed by lyophilization. The final powder is composed of particles ranging in size from 74  $\mu\text{m}$  to 640  $\mu\text{m}$ .” (page 5, lines 16-17). In describing the preparation of an implant, Bruce states that, “Implants were prepared by reconstituting 300 mg DMB with 0.7 ml of 1% rabbit serum albumin...in PBS to provide a thick paste. Either recombinant TGF-  $\beta$ 1 or carrier solution was then added to the paste....The implants were shaped into cylinders approximately 7 mm in diameter and 25 mm long.” (page 9, lines 54-58).

Bruce does not, however, describe a device that includes “a cortical bone section cut from a bone of a donor, said cortical bone section having impregnated therein an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor” as recited in claim 73, as amended.

As should be apparent, the features of claim 73 discussed above are not found in the Wayne or Bruce references. Accordingly, Applicants submit that independent claim 73, as amended, is novel over Wayne, Bruce and any of the other references of record. Applicants therefore respectfully requests withdrawal of the rejections of independent claim 73 under 35 U.S.C. 102(b).

Turning now to the rejection of claim 73 under 35 U.S.C. § 103(a) as being unpatentable over Grivas in view of Wayne and Bruce, Applicants submit that claim 73, as amended, is patentable over this combination. As stated above, claim 73 has been amended to recite, among other elements and features, “a bone dowel comprising a cortical bone section cut from a bone of a donor, said cortical bone section having impregnated therein an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor.” There is no disclosure or suggestion in any of the cited references to impregnate a cortical bone section cut from the bone of a donor with an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor, as recited in claim 73, as amended.

Applicants notes that “[t]o establish a *prima facie* case of obviousness, . . . there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.” MPEP §2142 (citing *In re Vaeck*, 20 USPQ.2d 1438 (Fed. Cir. 1991)). Additionally, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” MPEP §2141.02 (citing *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 USPQ 303 (Fed. Cir. 1983)).

Grivas et al. describes a dowel “provided by obtaining a plug from the shaft (diaphysis) of various long bones. The dowel has an intramedullary canal which can be packed with any of a variety of osteogenic materials.” (Abstract). As discussed above, Wayne and Bruce describe compositions that include a BMP powder mixed with TGF- $\beta$ , and possibly other ingredients, which can be formed into a desired shape. The respective references are devoid of any disclosure that would cause a person of ordinary skill in the art to make the modifications to Grivas that would be necessary to arrive at the invention set forth in claim 73, as amended. Moreover, Applicants submit that, even if a person of ordinary skill in the art were to consider combining the disclosure of Grivas and the disclosures of Wayne and Bruce, he or she would at most have considered use of the

Wayne or Bruce material as a coating for the bone dowel described in Grivas or as a packing for the cavity in the bone dowel described in Grivas. A person skilled in the art would not, however, derive any suggestion or motivation from the disclosures of Grivas, Wayne or Bruce to provide a bone dowel in which a “first osteogenic composition including a first substantially pure osteogenic factor” is impregnated in a “cortical bone section cut from a bone of a donor” as recited in claim 73, as amended. Indeed, the disclosure of Grivas itself provides evidence that the invention set forth in claim 73, as amended, is nonobvious. Given that Grivas is a patent application filed more than two years after the publication of Wayne and nearly two years after the publication of Bruce, the fact that Grivas is silent regarding the combination set forth in claim 73 supports the conclusion that this subject matter is nonobvious. Because the cited references alone or in combination, are devoid of any suggestion of impregnating a cortical bone section with any osteogenic composition, Applicants submit that the subject matter of claim 73 is patentable over this combination, and respectfully requests withdrawal of this rejection.

#### Independent claim 94

Independent claim 94 is also rejected in the outstanding Action as being unpatentable over Grivas in view of Wayne and Bruce. Claim 94 has been amended herein to specify that the “bone graft” recited therein comprises “a cortical bone section cut from a bone of a donor, said cortical bone section having impregnated therein an effective amount of a first osteogenic composition including a first substantially pure osteogenic factor.” Support for the amendment to independent claim 94 is found, for example, at page 13, lines 25-27; page 14, lines 27-29; and page 19, lines 7 and 21 of the as-filed application. Applicants submit that the subject matter of claim 94 is patentable over the cited combination for the same reasons that claim 73 is patentable over this combination, as discussed above. None of the cited references, either alone or in combination with one another, suggests or contains any teaching that might lead a person of ordinary skill in the art to impregnate a cortical bone section cut from a bone of a donor

with an osteogenic composition including a substantially pure osteogenic factor as recited in claim 94, as amended. The primary reference cited in the Action, Grivas, is devoid of any teaching or suggestion of impregnating an osteogenic composition into a cortical bone section cut from a bone of a donor, as recited in claim 94, and the secondary references, Wayne and Bruce, also fail to suggest this feature of claim 94.

Applicants therefore submit that claim 94, as amended, is in condition for allowance, and respectfully request withdrawal of the rejection thereof that is asserted in the outstanding Office Action.

#### Dependent Claims

Claims 2, 3, 74-75 and 77-93 depend, either directly or indirectly, from independent claim 73; and claims 95-109 depend, either directly or indirectly, from independent claim 94. Applicants submit that these dependent claims recite patentable subject matter for at least the same reasons that the subject matter of independent claims 73 and 94 are patentable, discussed above. Accordingly, Applicants respectfully request withdrawal of the rejections of dependent claims 2, 3, 74-75, 77-93 and 95-109 under 35 U.S.C. §§ 102(b) and 103(a). In addition, Applicants submit that additional reasons support the patentability of the dependent claims, and Applicants do not acquiesce in any assertion in the Action relating to the dependent claims; however, further discussion of same is considered unnecessary in view of the patentability of the independent base claims, as discussed above.

#### Withdrawn claims

Claims 110-116 were previously withdrawn from consideration on the grounds that they are drawn to a nonelected species and that there is no allowable generic or linking claim. Applicants respectfully request that claims 110-116 be reinstated and allowed on the basis that independent claim 94 is allowable.

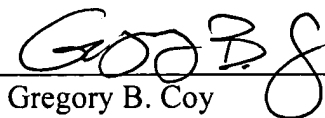
**Conclusion**

In view of the foregoing remarks, Applicants respectfully submit that the objections and rejections asserted in the outstanding Action are overcome. Accordingly, reconsideration leading to withdraw of all the rejections under 35 U.S.C. § 103(a) and allowance of this application, as amended, is respectfully requested.

If there are any remaining issues that can be addressed telephonically, the Examiner is invited to contact the undersigned to discuss the same. Nothing in this document is intended to be an admission that any of the cited references qualifies as prior art or that the arguments in support of patentability presented herein are the only reasons that the claims are in condition for allowance. Rather, Applicants expressly reserve the right to make showings at a later time to remove/disqualify one or more references from the prior art, if appropriate, and/or to present additional arguments in favor of patentability of the pending claims over the cited references.

Respectfully submitted,

By: \_\_\_\_\_



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